[Insert Reviewing Site Logo]

To: IRBs Considering Relying on [*Insert name reviewing IRB*]

From: *[Insert name of Study PI of Reviewing IRB]*

Date:

Protocol Title
Protocol Number:
Overall Study PI and institution: [*Insert if different than PI of reviewing IRB*]

You have expressed interest in relying on the [*Insert name reviewing institution*] IRB for the protocol listed above. [*Insert name reviewing institution*] is willing to consider this responsibility for this multi-site [*Insert study type- e.g. observational data only study, clinical trial*]. At this time I am providing you the associated information and documents so that you may review what is required to rely on the [*Insert name reviewing institution*] IRB review for this research. Please be sure to contact your IRB to ensure their process to rely on other IRB is followed appropriately. Here is a summary of the process:

1. The [*Insert name reviewing institution*] IRB has reviewed and approved the referenced protocol. In order to add your site as a relying site the [*Insert name reviewing institution*] IRB will need a reliance agreement and other information from each site.
2. If you decide to rely on the [*Insert name reviewing institution*] IRB review we will also ask you to provide us any information that is specific to your institution including state laws that require IRB consideration. However, the [*Insert name reviewing institution*] IRB cannot consider general requests for modifications of the protocol. Only local context human subject related issues will be considered.
3. There are agreements and forms that will need to be completed to invoke reliance. I have attached these documents so that you can understand the terms of the reliance agreement. The documents are as follows:
    a. **Master Common Reciprocal Institutional Review Board Authorization Agreement-** This agreement specifies the responsibilities and expectations for the reviewing IRBs and relying IRBs, and must be signed by an authorized institutional official at your site. *Your IRB office should be contacted and facilitate this process.* OR *[Insert Relying Institution]* is already a participating member of the *Master Common Reciprocal Institutional Review Board Authorization Agreement, and the agreement is on file.*
    b. **MRA Determination Form-** This form is required for each protocol utilizing the Master IRB Authorization Agreement. It includes protocol specific information, as well as assurances related to Local Ancillary Reviews, Conflicts of Interest, and Research Staff Training.
    c. **IRB Site Survey-** This web based survey includes information that is specific to the reviewing and relying sites. It includes background information that we will need from your site if we assume responsibility for the IRB review of your site. Once an institution has participated as a reviewing or relying site in a PEDSnet

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study, the survey information will be catalogued and made available to prepopulate future study surveys. Enter the study title and sponsor listed in the heading of this letter

4. One of the attached documents is the PI responsibilities for both the reviewing and relying sites. Please be sure to review these responsibilities as they explain how the PIs' oversight responsibilities differ when working under an IRB reliance agreement.
5. Approved versions of the consent forms are attached. You will be asked to insert institutional specific consent statements for HIPAA language, local contacts, statements regarding research-related injury and any COI disclosures. In addition, you will be asked to accept or amend the information regarding whether research consents form will be put in medical records. A final consent will be approved specifically for your institution with your required language for these sections only. All other sections will reflect the consent form that the [*Insert name reviewing institution*] IRB has approved. Please insert the sections that are indicated in red. You will receive an approved copy once finalized by the [*Insert name reviewing institution*] IRB.
6. The attached forms should be completed and returned to *** at [*Insert name reviewing institution*] and s/he will submit them to the *[Insert name reviewing institution*] IRB to add your site as an amendment when appropriate. You will be notified when approval for your site is final and you will be provided with the consent form that will need to be used. No work may begin at your site until you have been notified about your site's approval and been provided with the consent form approved for your institution

Please contact *** if there are any questions regarding this process